

REMARKS

Claims 128, 130-132, and 135-148 are pending in this application. Claims 128 and 136-141 are rejected under 35 U.S.C. § 102(b) for anticipation by Constantz et al. (U.S. Patent No. 5,336,264; hereinafter “Constantz”) and claims 130 and 135 are rejected under 35 U.S.C. § 103(a) for obviousness over Constantz. The Examiner also objects to the drawings filed on April 12, 1999 under 37 C.F.R. § 1.84 or 1.152. The Examiner objects to claims 131, 132, and 142-148, but acknowledges that these claims would be allowable if rewritten in independent form, including all of the limitations of the base claim and any intervening claims. By this reply, Applicants amend claims 128, 130, 135, and 141, and address each of the Examiner’s objections and rejections below.

Support for the Amendment

Claims 128, 130, 135, and 141 are amended to clarify the claimed subject matter. No new matter is added by the amendment.

Objection to the Drawings under 37 C.F.R. § 1.84 or 1.152

In response to the Examiner’s objection to the drawings for the reasons indicated by the draftsman on Form PTO-948, Applicants submit corrected drawings in compliance with 37 C.F.R. § 1.84 and 1.152. Therefore, this objection can be withdrawn.

Rejection under 35 U.S.C. § 102(b)

The Examiner rejects claims 128 and 136-141 under 35 U.S.C. § 102(b) for anticipation

by Constantz, stating that Constantz discloses a composition comprising calcium phosphate in which a variety of additives, such as bone associated proteins, “may be added to modify the physical properties of the composition, enhance resorption, bone formation, growth of osteoclasts and/or osteoblasts, etc.” (pp. 3-4 of the Office Action dated September 16, 2003). As was discussed in the previous Reply to Office Action, dated March 15, 2004, claim 128 recites an implant composition containing three components: a calcium phosphate, a first agent that directly or indirectly stimulates osteoclast activity, and a second agent that is biologically active. The present amendment to claim 128 clarifies that the first and the second agents are different.

The first agent of the implant composition of claim 128, which directly or indirectly stimulates osteoclast activity, is provided to aid in the resorption rate of the implant composition, while the second biologically active agent is included in the implant composition to aid in the diagnosis of disease, to cure, mitigate, treat, or prevent a disease, or to enhance the physical or mental development or condition of the recipient of the implant composition (see, e.g., page 35, lines 4-10, and page 56, lines 18-21). By amending claim 128 to recite that the first agent is different from the second agent, Applicants clearly distinguish the present invention of claims 128, 130-132, and 135-148 from the calcium phosphate cement composition disclosed by Constantz.

As was discussed in the previous Reply to Office Action, dated March 15, 2004, Constantz merely describes a hydroxyapatite bone cement that may optionally contain an additive, e.g., a protein, which modifies the physical properties of the bone cement. Constantz fails to teach or suggest that the bone cement contains two agents, an agent that directly or indirectly stimulates osteoclast activity and a second agent that is biologically active.

The M.P.E.P. § 2131 states that “‘A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference.’ *Verdegaal Bros. v. Union Oil Co. of California* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).” It is also established that when the claimed combination is not specifically named in the prior art, but instead, it is necessary to select portions of the teachings within a reference and combine them, anticipation can only be found if the classes or substituents are sufficiently limited or well delineated. See M.P.E.P. § 2131.02, citing *Ex parte A* 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). The Federal Circuit in *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.* stated that “although specific claims are subsumed in a [prior art reference’s] general disclosure...this is not literal identity.” 24 USPQ2d 1321 (1992). Thus, when a reference does not provide guidance on how to construct a product with the claimed beneficial properties, it is not anticipatory.

Constantz fails to teach or suggest that the composition contains both a first and a second agent, as is recited in present claim 128, and claims dependent therefrom. Moreover, to further distinguish present claims 128, 130-132, and 135-148 from Constantz, Applicants have amended claim 128 to recite that the two agents are different, thereby clarifying that the limitation of two agents cannot be satisfied by a composition that contains only one agent. Because Constantz fails to teach or suggest an implant composition containing all of the components recited in present claim 128 (i.e., a calcium phosphate, a first agent that directly or indirectly stimulates osteoclast activity, and a second agent that is biologically active), Applicants respectfully request that the rejection of claims 128 and 136-141 under 35 U.S.C. § 102(b) for anticipation by Constantz be withdrawn.

Rejection under 35 U.S.C. § 103(a)

Claims 130 and 135 stand rejected under 35 U.S.C. § 103(a) for obviousness over

Constantz. The Examiner states:

The prior art does not teach the specific claimed agents as described in claims 130 and 135.

It would have been obvious to one [sic] ordinary skill in the art at the time the invention was made to used [sic] any of the claimed agents as described. Column 6, lines 52-58 teach that other proteins associated with other parts of the human or other mammalian anatomy can be employed in the composition. The agents described in claims 130 and 135, i.e., parathyroid hormone and growth factors are proteins found in human anatomy, which in turn can be used in the present invention. (Office Action, p. 3.)

Applicants respectfully traverse this rejection.

The M.P.E.P. § 2143.03 states:

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Constantz fails to teach or suggest any of the agents recited in claims 130 or 135.

Constantz merely states that “a wide variety of proteins may be included in the medium to provide for specific properties” and generically refers to “[o]ther proteins associated with other parts of human or other mammalian anatomy...” (see col. 6, lines 38-40 and lines 52-53).

Therefore, Constantz merely specifies the use of a broad genus of human or mammalian proteins, but does not teach or suggest any of the protein species disclosed in Applicants’ claims 130 and 135. The case law is clear with respect to genus-species relationships: the fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness (*In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed.

Cir. 1994)). “The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.” (See, *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992).)

Because Constantz discloses a broad genus of human or mammalian proteins but fails to teach or suggest any of the protein species recited in Applicants’ claims 130 and 135, Constantz does not teach or suggest all of the elements of claims 130 and 135, as is required (see M.P.E.P. § 2143.03, *supra*). For this reason, the Examiner has not satisfied all of the criteria for establishing a *prima facie* case of obviousness. Accordingly, Applicants respectfully request that the rejection of claims 130 and 135 under 35 U.S.C. § 103(a) for obviousness be withdrawn.

CONCLUSION

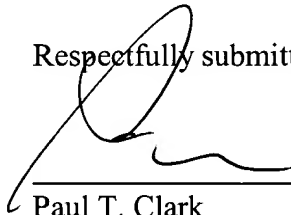
In view of the above remarks, Applicants respectfully submit that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for three months, to and including October 8, 2004, and a check for the fee required under 37 C.F.R. § 1.17(a).

If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Date: Oct. 6, 2004

Respectfully submitted,



Paul T. Clark
Reg. No. 30,162

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045